PULSATILE RELEASE COMPOSITIONS OF MILNACIPRAN

Abstract of the Invention

A once-a-day oral milnacipran pulsatile release composition has been developed that releases the drug in spaced apart "pulses". The dosage forms are comprised of first, second and optional third dosage units, with each dosage unit having a different drug release profile. This dosage form provides *in vivo* drug plasma levels characterized by C_{max} below 3000 ng/ml, preferably below 2000 ng/ml, and most preferably below 1000 ng/ml. These levels help to avoid stimulation of the cholinergic effects on the CNS. The composition allows milnacipran to be delivered over approximately 24 hours, when administered to a patient in need, resulting in diminished incidence or decreased intensity of common milnacipran side effects such as sleep disturbance, nausea, vomiting, headache, tremulousness, anxiety, panic attacks, palpitations, urinary retention, orthostatic hypotension, diaphoresis, chest pain, rash, weight gain, back pain, constipation, vertigo, increased sweating, agitation, hot flushes, tremors, fatigue, somnolence, dyspepsia, dysoria, nervousness, dry mouth, abdominal pain, irritability, and insomnia.

1308740_v1